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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/177,387	10/23/1998	JAMES L. HARTLEY	0942.2850004	3052

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EXAMINER	
LAMBERTSON, DAVID A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/177,387	Applicant(s) HARTLEY ET AL.	
	Examiner David Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the c ver sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *100-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *100-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s) _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 26, 28-35, 52 and 89-99 are cancelled as per Applicant's request. Newly entered claims 118-127, and amended claims 100-102 are acknowledged. Claims 100-127 are to be examined in the pending application.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Applicant refers to "related" applications 08/663,002 and 08/486,139 in the first line of the instant application, but does not disclose in what way these applications are related to the instant application (i.e., are they continuations, CIPs, divisionals). Additionally, no claim to priority of these documents is noted in the declaration. Furthermore, Office records do not indicate that there is a direct relation between the instant application and the aforementioned applications. Clarification is necessary. Absent evidence to the contrary, priority is only granted with respect to provisional application 60/065,930.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 100-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley, et al., (WO 96/40724) in view of Shuman (US Patent No. 5,766,891). (Examiner's note: WO 96/40724 is not referred to as a priority document in the instant application, either in the

specification or the declaration. Furthermore, applicant on the WO 96/040724 publication is not the same as the inventive entity on the instant application, in the event priority is to be claimed).

Applicant's invention with regard to the aforementioned claims reads on a method for synthesizing a double stranded nucleic acid molecule, essentially via PCR involving the use of primers comprising recombination sites wherein the recombination sequences are defined by the removal of one or more stop codons (claims 100, 103, 106, 109, 115 and 115), the aversion of hairpin formation by the recombination sequence (claims 101, 104, 107, 110, 113 and 116), SEQ ID Nos. 1-16 (claims 102, 105, 108, 111, 114 and 117), sequences with 80-99% homology to SEQ ID Nos. 1-16 (claims 119, 121, 123, 125 and 127), or sequences with 80-99% homology to SEQ ID Nos. 39-43 (claims 118, 120, 122, 124 and 126). Further limitations to the claims include: selection of the recombination sites from *att*B, *att*P, *att*L, *att*R, *lox*P, or portions of these sites, location of the recombination sites at or near one terminus of the synthesized molecule, further amplification of the synthesized molecules, location of the recombination sites at or near one or both termini of the synthesized molecule, and wherein the recombination sites do not recombine with each other.

Hartley, et al., discloses sequences that are identical to each of those of the instant application, thereby anticipating the sequences (for example SEQ ID No. 5 of the instant application is 100% identical to SEQ ID No. 5 of WO 96/40724, and SEQ ID No. 39 is identical to SEQ ID No. 6 of WO 96/40724 because the variable nucleic acid residues of SEQ ID No. 39 read on those that are present in SEQ ID No. 6). Furthermore, these sequences are derived from *att* recombination sites and have the inherent property that they will not all recombine with each other (owing to differences in the individual sequences; see page 43, lines 24-25 of the instant

application), therefore those limitations are also anticipated by the identity of these sequences. In addition, the *att* recombination sites contain multiple stop codons and have the ability to form hairpin structures (see page 41-42 of the instant application) that are eliminated by the mutations defined in the sequences disclosed in the instant application. Therefore, the sequences disclosed in Hartley, et al., inherently have these properties due to sequence identity with the sequences of the instant application. Hartley, et al., does not disclose the use of these sequences in primers for the amplification of double stranded nucleic acid molecules.

Shuman discloses the use of primers with specific sequences to amplify nucleic acid molecules comprising those specific sequences for use in cloning procedures (see column 6, lines 46-56). The concept of primers inherently includes the property that the sequences used therein are located at or near one (or both) termini of the nucleic acid molecule that is produced. Further amplification of the molecule simply requires the substitution of the nucleic acid molecule that is produced as the template for another round of amplification, and is therefore inherent to the method described by Shuman.

Hartley, et al., is modified by Shuman to include the sequences represented by SEQ ID Nos. 1-16 and 39-43 in the PCR method used for the production of a double stranded nucleic acid molecule. The ordinary skilled artisan would have been motivated to combine these teachings in order to develop a cloning system that was free of the use of restriction endonucleases, thereby providing a more efficient method of cloning. It would have been obvious to combine these teachings because the addition of recognition sequences (restriction sites, the topoisomerase sequence site disclosed in Shuman, etc.) to primers for the purpose of

cloning is a convenient way of modifying the sequences to contain elements of interest, which is clearly described in Shuman, as indicated above.

Given the teachings of the stated prior art and the level of skill of the ordinary skilled artisan at the time of the applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
September 22, 2002

DAVID GUZO
PRIMARY EXAMINER